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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
11/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,687	CHEUNG, WING SUM	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/09 has been entered.

Response to Reply

Applicant's reply filed 8/31/09 is acknowledged. No claims have been amended, added, or canceled in this reply. Claims 1-11 and 14-16 remain pending in the current application, all of which are being considered on their merits. References not included with this Office action can be found in a prior action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to “a rabbit skin … possessing a specific alteration of rhythm in environmental temperature activity [SART] of 0.5 iu/g or more,” which is confusing. The product-by-process steps in claim 1 appear to yield an extract of rabbit skin, not rabbit

skin *per se*. The steps actually appear to require destruction of the skin. Because claims 2-11 and 14-16 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 6 requires that the vaccinating of the skin be carried out by "subcutaneous" injection, which is confusing because all that is required for claim 1 is skin. It is not clear how skin can be injected below the skin. Clarification is required.

Claims 14 and 15 require that the rabbit skin of claim 1 be extracted, processed, and eluted, but it is not clear whether these steps are to be substituted for those of claim 1 or added to them. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 14-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shibayama et al. (1991, U.S. Patent 5,057,324).

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (column 1, lines 45-65) and removing the skin (Example 1 at column 2, line 57, et seq.). Shibayama teaches treating the skin first with sodium hydroxide (an alkali) and then with hydrochloric acid, then subjecting it to ultrafiltration to remove substances of molecular

weight greater than 20kDa (column 3, lines 1-12). Shibayama teaches adding distilled water to the resulting ultrafiltrate (column 3, lines 13-22) and claim a composition comprising the product and a pharmaceutically acceptable carrier (claim 8).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since

in spite of the fact that the claim may recite only process limitations, **it is the patentability of the product claimed and not of the recited process steps which must be established.** We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, there is no evidence on the record that the strain of vaccinia virus or the strain of rabbit has any effect on patentability. The data in the table at page 14 is noted, but there is no evidence that the variations in base and amino acid composition from the different combinations has any effect on the patentability of the product, e.g. an effect on SART that affects patentability.

M.P.E.P. § 2112 reads, "The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." Something that is old does not become patentable upon the discovery of a new property, use, or application. Therefore, even if applicant had discovered a new

property of Shibayama's composition, which the examiner does not concede, that composition would not become patentable.

Applicant alleges that the examiner has taken official notice of properties of Shimayama's composition. See reply, page 7, first paragraph. However, the examiner's statements at pages 3-4 of the Office action do not constitute official notice (which relates to statements about common knowledge in the art), but are rather an application of agency-approved caselaw pertinent to product-by-process claims. See M.P.E.P. § 2113. Applicant has chosen to describe the claimed composition in terms of its method of making; this manner of claiming is accompanied by a burden on the applicant, not on the examiner, to show that the steps produce a materially different product than that taught by Shibayama.

Quite to the contrary, it is applicant who attempts to take official notice of facts that are allegedly well known in the art. See page 8, first paragraph, where applicant alleges without basis that it is well known that "the performance of a bio-product is decided by the constituent bio-active substances and that the bio-active substances are determined by a specific process" and that "a vaccine can be produced by inoculation with a virus" but "many experiments are necessary." These comments are not supported by evidence or declarations of those skilled in the art. Furthermore, they do not appear to pertain to the claims, which are not drawn to a vaccine *per se*.

Applicant alleges generally that the steps within the instant claims are "a completely different process that results in a completely different substance." See reply, page 7, last paragraph. Applicant further details the differences between the method

employed by Shibayama and that claimed. See page 8, last paragraph, through page 9. These arguments have been fully considered, but they are not persuasive. As has been discussed above and in previous Office actions, the invention being examined is a product, not any method of making the same. The examiner has stipulated that the steps Shimayama used to make the prior art product are not identical to the steps recited in the instant claim; however, a side-by-side comparison of the processes cannot suffice to show patentability of the product. There is no evidence on the record that Shimayama's composition does not possess the claimed SART property; the fact that Shimayama did not assay for such a property is not evidence that it is lacking in Shimayama's product. See *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987) and *Titanium Metals Corp. v. Banner,* 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

As discussed previously and above, this rejection would be overcome by applicant submitting substantive evidence that the claimed process steps impart distinctive structural characteristics to the product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 14-16 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shibayama et al. (1991, U.S. Patent 5,057,324).

Shibayama teaches a rabbit skin extract that has inhibitory activity against kallikrein formation, wherein the substance is useful as a drug (abstract). The substance is obtained by infecting a rabbit skin with vaccinia virus (column 1, lines 45-65) and removing the skin (Example 1 at column 2, line 57, et seq.). Shibayama teaches treating the skin first with sodium hydroxide (an alkali) and then with hydrochloric acid, then subjecting it to ultrafiltration to remove substances of molecular weight greater than 20kDa (column 3, lines 1-12).

Although the reference does not expressly teach all of the limitations regarding how the rabbit skin is produced, these limitations are considered to be product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

The reference does not explicitly teach feeding the rabbit. However as a matter of standard protocol, animals used in laboratory experiments are required to be treated humanely which includes feeding of the animals. Thus, while the reference does not expressly state the rabbits were fed, it would have been a matter of standard procedure to do so, and thus obvious to one of ordinary skill in the art.

The reference does not teach each of the claimed strains of vaccinia, types of rabbit, wherein the inflammation reaches the claimed point, or SART activity of the skin. However, at the time of the claimed invention, each of the claimed strains and rabbits were well known and used in the art for animal and laboratory experiments. Thus, it would have been within the purview of one in the art to use any of the instant strains or rabbits as a matter of routine practice. Regarding the SART activity, the skin of the art is the same as that claimed, thus it must intrinsically exhibit the claimed activity.

The reference does not teach the amount of virus injected into the rabbit. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such injections as a matter of routine experimentation. Thus, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of virus injected into the rabbit with a reasonable expectation for successfully obtaining an effective extract against the formation of kallikrein.

The reference does not teach water as the pharmaceutically acceptable carrier. However, at the time of the claimed invention, water was a well known and recognized carrier. Thus it would have been obvious to one of ordinary skill in the art to combine the extract with water in following the teachings of Shibayama.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicants rely on arguments traversing the above rejection to traverse this rejection. Therefore, the response set forth above to arguments also applies to this

rejection. It is noted as a matter of form that applicant's arguments regarding the section 103 rejection do not comply with 37 C.F.R. 1.111, which requires that the reply distinctly and specifically point out the supposed errors in the examiner's action and reply to every ground of objection and rejection in the prior Office action. Rejections under section 103 are distinct from those under section 102, so different arguments are appropriate. A future response that similarly omits substantive discussion of a rejection will be considered a nonresponsive reply.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651